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10/677,441	10/02/2003	Anne-Marie Stomp	5051-337DVCT3	9042
20792 7590 01/26/2010 MYERS BIGEL, SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER ZHENG, LI				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Please note that the examiner's answer filed on 4/3/2008 is vacated and replaced by the one as follows to comply with the order returning the undocketed appeal to the examiner.

Please note that the IDS filed on 2/17/2009 and 6/19/2009 have been considered.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/677,441

Filing Date: October 02, 2003

Appellant(s): STOMP ET AL.

Field Code Changed

Alice Bonnen
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 19 November 2007.

(1) Real Party of interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

On page 4 of the Appeal Brief, under item 4, Appellants present the rejection of claim 11 and 32 on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. Rejection 4 is withdrawn. As stated in part IV of Appellants' argument in the appeal brief (page 23), Appellants believe that the rejection was originally intended to cite the application No.10/873,846, not U.S. Patent No. 6,815,184. Appellants are correct in this regard. US patent Number 6, 815,184 was cited in this rejection instead of 10/873,846 due to an inadvertent error. However this issue is moot, as upon further consideration, this rejection is now withdrawn.

Appellant's brief does not include a statement regarding the grouping of the claims therefore claims 1-40 stand or fall together.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US patent Number 6, 815,184;

US Patent Application Number 10/873,846 (now abandoned) and 11/778,480

(co-pending);

Dieryck et al. 1995, Transfus. Clin. Biol. 2:441-447.

(9) Grounds of Rejection

Grounds of Rejection

I. Claims 1-10, 12-31 and 33-40 on appeal stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 22-25 of U.S. Patent No. 6,815,184.

First, the Examiner further confirms that claims 1-17 of the US patent Number 6,815,184 (hereafter "the '184 patent") were intended to be referred to in this double patenting rejection and not claims 22-25.

Instant claims 1-10, 12-28 and 30-40 are drawn to a stably transformed duckweed plant or plant tissue comprising a nucleic acid of interest incorporated in its genome; or wherein said duckweed plant comprises fewer than 5 copies of said heterologous nucleic acid of interest; or wherein said duckweed is Lemma minor; or wherein said nucleic acid comprises at least one selection marker gene; or wherein said nucleic acid comprises two genes of interest; or wherein said nucleic acid encodes α -interferon; or wherein said nucleic acid encodes a secreted protein; or wherein the plant tissue is meristematic tissue, frond tissue, callus tissue, or Type I callus tissue; or wherein the nucleic acid of interest is chimeric.

Claims 1-17 of '184 patent teach a method of producing biologically active α -2b-interferon in a duckweed plant culture or a duckweed nodule culture, comprising the steps of: (a) culturing within a duckweed culture medium a duckweed plant culture or a duckweed nodule culture, wherein said duckweed plant culture or said duckweed nodule culture is stably transformed to express said biologically active α -2b-interferon, and wherein said biologically active α -2b-interferon is expressed from a nucleotide sequence comprising a coding sequence for the polypeptide and an operably linked coding sequence for a signal peptide that directs secretion of the α -2b-interferon into the culture medium; and (b) collecting said biologically active α -2b interferon from the duckweed culture medium. Claims 1-17 of '184 patent also teach that said biologically active α -2b-interferon is secreted into the duckweed culture medium. Claims 1-17 of '184 patent further teach that *Lemna minor*-preferred codons is used to express α -2b interferon.

Although claims 1-17 of '184 patent do not explicitly teach that said duckweed plant comprises fewer than 5 copies of said heterologous nucleic acid of interest; that said nucleic acid comprises at least one selection marker gene; that said nucleic acid comprises two genes of interest, or that the nucleic acid of interest is chimeric, they are inherently present in a transformed duckweed plant expressing α -2b-interferon. The promoter of human α -2b interferon gene would not work in plant, therefore α -2b-interferon expression cassette should be a chimeric one with α -2b interferon gene operably linked to a plant promoter. Further, said transgenic duckweed plant would normally comprise a selection marker in addition to the chimeric α -2b-interferon

cassette, as selection markers are routinely included in plant transformation to identify successful transformation events. Further, transgenic plants would normally have at least one copy of said heterologous nucleic acid of chimeric α -2b-interferon cassette.

Although claims 1-17 of '184 patent do not explicitly teach that the duckweed plant/ tissue is from *Lemna minor*, or that plant tissue is meristematic tissue, frond tissue, callus tissue, or Type I callus tissue, those limitations are regarded as obvious design choices because *Lemna minor* is an important duckweed species and claims 1-17 of '184 patent teach that *Lemna minor*-preferred codons are used to express α -2b interferon. Further those particular tissues as claimed are the tissues commonly used by the researchers in that art for various purposes such as tissue-culturing or transformation.

Appellants' Argument and Examiner's Response:

Appellants argue that the MPEP is clear that the reason for a double patenting rejection is to prevent the unjustified timewise extension of the right to exclude granted by a patent (Appeal Brief, page 5, last paragraph), and that the extension of patent term is not an issue in this case (Appeal Brief, page 5, 1st full paragraph to page 6, 1st full paragraph).

However, Appellants narrowly interpret the purpose for a double patenting rejection. MPEP clearly states that "The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the

statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent *and to prevent possible harassment by multiple assignees*" (emphasis added; see MPEP Form Paragraph 8.33). Therefore preventing the unjustified timewise extension time is not the sole purpose.

Appellants further argue that whenever the courts have discussed the concern of harassment by multiple assignees it has always been in terms of commonly owned patents that might subsequently be assigned or transferred to different parties (Appeal Brief, page 6, last paragraph) and that '184 patent and instant application at issue were never commonly owned so that the issue of harassment by multiple assignees does not apply to this case (Appeal Brief, page 7, 1st paragraph).

Appellants appear to be arguing that common ownership of a patent application and the reference over which an obviousness-type double patenting rejection is made, is a prerequisite for the rejection. However, it is not a prerequisite. Further, according to MPEP § 804, chart II-B, an obvious double patenting rejection is appropriate when an application and a patent have at least one common inventor and no common assignee. Therefore, having common assignee is not a requirement for making an obviousness-type double patenting rejection.

Appellants argue that MPEP 804.03 IV regarding rejections under 35 U.S.C. § 102 and 103 governs the present situation (Appeal Brief, page 7, 2nd full paragraph). However, rejections under these statutes are not applicable here. Appellants argue that

the claims of the '184 patent should have been provisionally rejected under U.S.C 103 (a) as obvious over the present application, which was copending during the prosecution of the '184 patent (Appeal Brief, page 7, 3rd paragraph). Appellants further argue that the Examiner overlooked the fact that the present application has an earlier effective filing date over that of the '184 patent and that the application that matured into the '184 patent application was determined by USPTO to be both novel and non-obvious over the prior art including the PCT counterpart of the present application (Appeal Brief, page 8, 1st paragraph)

The Examiner did not overlook the fact that the present application has an earlier effective filing date over that of the '184 patent, or else rejections under 35 U.S.C. 102 or 103 would have been made. Further, the lack of a double patenting rejection during the prosecution of '184 does not preclude a rejection from being made here.

Appellants review the CREATE Act and admit that they cannot take advantage of the provisions of the CREATE Act since there was no joint research agreement in place between the assignees of the present application and of the '184 patent at the time of the invention of the present application. Appellants argue that double-patenting rejection under the CREATE Act does not apply to the present application and the rejection should be withdrawn (Appeal Brief, paragraph bridging pages 8-9, to page 10, 1st full paragraph).

However, that the CREATE Act Safe-Harbor Provisions do not apply to the present application does not preclude an obviousness-type double patenting rejection from being applicable. The Create Act addresses the situation in which there was a joint research agreement in place between different assignees at the time of the invention. However, it does not preclude a double patenting rejection from being made if no such agreement was in place.

Appellants argue that MPEP 804(II)(B)(1) indicates that an obviousness-type double patenting rejection is applicable in a commonly owned patent, in a non-commonly owned patent subject to a joint research agreement, and when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent (Appeal Brief, paragraph bridging pages 10-11). However, the flowchart in MPEP 804, Chart II-B indicates that an obviousness-type double patenting rejection is applicable when there is at least one common inventor, no common assignee, and no joint research exclusion under 35 U.S.C. 103(c). Further, as discussed above, a double patenting rejection is also to be made to prevent possible harassment by multiple assignees. Appellants further argue that both MPEP § 804.03 (IV) and Chart II-B in § 804 indicates that a double patenting rejection is appropriate when the reference application or patent is prior art against the patent application at issue. Appellants further emphasize that the term "AND" noted in Chart II-B is clearly intentional, which supports that the rejections as outlined in Chart II-B cannot be made if the '184 patent does not qualify as prior art (Appeal Brief, page 11, last paragraph).

The Examiner does not agree with Appellants' interpretation of the MPEP. It is clearly cited in MPEP § 804 section III, 6th paragraph that "An examiner should make both a 35 U.S.C. 102(e)/103 rejection and a double patenting rejection over the same reference when the facts support both rejections". Therefore, it is clear that whether the patent at issue is prior art or not is not a prerequisite for making a double patenting rejection. In the instant case, the Examiner did not make a 35 U.S.C. 102(e)/103 rejection simultaneously because the present application has an earlier effective filing date over that of the '184 patent.

Appellants further argue that even if a double patenting rejection were proper, the appropriate test is the two-way obviousness test according to MPEP § 804 (II)(B)(1)(b) (Appeal Brief, pages 12-13).

However, a two way obviousness test is to determine whether extension of patent term is justified or not, which is not an issue in instant case. Further, two-way test is to be applied only when the applicant could not have filed the claims in a single application and there is administrative delay. However, Appellants do not meet the initial burden to show why Appellants could not file all the claims in a single application or that there is an administrative delay during the prosecution of instant application. Therefore, the request by Appellants to conduct two-way obvious test is not granted.

Applicants argue that the improvement in later filed application that matured into the '184 patent could not have been presented in the present application as the '184 patent claims an invention not disclosed in the present application, that the later filed

invention was not conceived until after the present application was filed, and that the applications are owned and prosecuted by different assignees (Appeal Brief, page 21, the 2nd paragraph from the bottom).

The instant application claims a duckweed plant expressing α -interferon, whereas the '184 patent claims a method to produce α -2b interferon by using a transgenic duckweed plant expressing α -2b interferon. However, at the time of the filing of instant application, it was well known in the art that α -2b interferon could be used to treat diseases such as chronic hepatitis C and that the sequence of human α -2b interferon gene was available to be used for heterologous expression. The invention as claimed in '184 patent could have been included in instant application. Further, although the applications are owned and prosecuted by different assignees, they still share one common inventor who has the knowledge about both applications.

II. Claims 11 and 32 on appeal stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. (1995, Transfus Clin Biol. 2:441-447).

Claims 1 and 20, on which claims 11 and 32 are dependent, are discussed as above. Claims 11 and 32 further contain the limitation that said gene of interest is a hemoglobin, collagen, P450 oxidase or monoclonal antibody.

Claims 1-17 of '184 patent do not teach hemoglobin, collagen, P450 oxidase or monoclonal antibody.

Dieryck et al. teach use of a transgenic plant to produce recombinant hemoglobin (abstract).

It would have been obvious for a person with ordinary skill in the art to modify the method of claim 1 or 20 of '184 patent to express hemoglobin instead of α -interferon, resulting in the instant invention. One would have been motivated to do so given the teaching of Dieryck et al. that using transgenic plant to produce hemoglobin allows low cost with minimal risks of pathogen contamination (abstract).

Appellants' Argument and Examiner's Response:

Appellants repeat the same argument as discussed above (Appeal Brief, pages 14-22). These arguments are not found persuasive for the reasons discussed above.

III. Claims 1-10, 12-31 and 33-40 on appeal stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 22-25 of U.S. Patent Application No. 11/778,480.

Instant claims 1-10, 12-31 and 33-40 are drawn to a stably transformed duckweed plant or plant tissue comprising nucleic acid of interest incorporated in its genome; or wherein said duckweed plant comprises fewer than 5 copies of said heterologous nucleic acid of interest; or wherein said duckweed is Lemma minor; or wherein said nucleic acid comprises at least one selection marker gene; or wherein said nucleic acid comprises two genes of interest; or wherein said nucleic acid encodes α -

interferon; or wherein said nucleic acid encodes a secreted protein; or wherein the plant tissue is meristematic tissue, frond tissue, callus tissue, or Type I callus tissue; or wherein the nucleic acid of interest is chimeric.

Claims 1, 22-25 of U.S. Patent Application No. 11/778,480 (hereafter '480 application) teach a duckweed plant culture or a duckweed nodule culture stably transformed to express biologically active α -2b-interferon and an operably linked coding sequence for a signal peptide capable of directing secretion of the α -2b-interferon. Claims 1, 22-25 of '480 application also teach that the duckweed is *Lemna* minor (claim 25) and signal polypeptide is rice α -amylase signal polypeptide.

Although claims 1, 22-25 of '480 application do not explicitly teach that said duckweed plant comprises fewer than 5 copies of said heterologous nucleic acid of interest; that said nucleic acid comprises at least one selection marker gene; that said nucleic acid comprises two genes of interest, or that the nucleic acid of interest is chimeric, they are inherently present in a transformed duckweed plant expressing α -2b-interferon with rice α -amylase signal polypeptide. The promoter of human α -2b-interferon gene would not work in plant, therefore α -2b-interferon expression cassette must be a chimeric one with α -2b interferon gene operably linked to a plant promoter. Further, said transgenic duckweed plant would normally comprise a selection marker in addition to the chimeric α -2b-interferon cassette, as selection markers are routinely included in plant transformation to identify successful transformation events. Further transgenic plants would normally have at least one copy of said heterologous nucleic acid of chimeric α -2b-interferon cassette.

Although claims 1, 22-25 of '480 application do not explicitly teach that plant tissue or nodule tissue is meristematic tissue, frond tissue, callus tissue, or Type I callus tissue, those limitations are regarded as obvious design choices because those particular tissues are commonly used by researchers in the art for various purposes such as tissue culturing or transformation.

Appellants' Argument and Examiner's Response:

Appellants argue that since the rejection is provisional and Appellants show intention to address the rejection once claims are issued from the copending application 11/778,480 (hereafter "the '480 application"), withdrawal of the rejection is requested (Appeal Brief, page 23, 2nd paragraph).

However, since the instant rejection is not the only remaining rejection, the rejection is still maintained.

IV. The rejection of claims 11 and 32 on appeal on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. (1995, Transfus Clin Biol. 2:441-447) is withdrawn.

Appellants believe that the rejection was originally intended to cite the application No.10/873,846, not U.S. Patent No. 6,815,184 (page 23). Appellants are correct in this regard. US patent Number 6, 815,184 was cited in this rejection instead of 10/873,846

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due to an inadvertent error. However this issue is moot, as upon further consideration, this rejection is now withdrawn.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Li Zheng/

Examiner, Art Unit 1638

/Ashwin Mehta/

Primary Examiner, Art Unit 1638

/Anne Marie Grunberg/

Supervisory Patent Examiner, Art Unit 1638

/GARY BENZION/

Supervisory Patent Examiner, Art Unit 1637

